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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,041	09/10/2001	Gerard T. Hardiman	DX0724XK1	2187

28008 7590 04/28/2004

DNAX RESEARCH, INC.  
LEGAL DEPARTMENT  
901 CALIFORNIA AVENUE  
PALO ALTO, CA 94304

EXAMINER
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HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO 802)

4) ☐ Information Statement (PTO 412)

### **Detailed Office Action**

1a. Receipt of Applicants' amendment and arguments filed on 29 January 2004 is acknowledged. Claim 1 has been amended, claims 2-22 have been canceled and new claims 23-26 have been added. Thus claims 1, 23-26 are pending and under consideration.

1b. Receipt of Applicants' declarations under 37 C.F.R. §1.132, filed by Dr. McClanahan on 29 January 2004 is also acknowledged.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 01/29/2004:

(I). Information Disclosure: References AE, AQ, AR, AS, AT, AU, AV, AW, AX, AZ, BD, BE, BF, BI, BJ, BK, BL, BN, BP and BR, cited in the information disclosure statement filed on 06 May 2002 have been considered and initialed.

(II). The objection of claim 1 for reciting non-elected SEQ ID Nos, is withdrawn.

(III). The rejection of claim 1 made under 35 U.S.C. §112, second paragraph is withdrawn.

#### ***Claim Rejections under 35 U.S.C. §101/112:***

3a. Claim 1 stands rejected and new claims 23-26 are rejected under 35 U.S.C. §101 for reasons of record set forth in the office action mailed on 29 September 2003, pages 4-8.

Applicants argue that the claimed DNAX TLR6 polypeptide corresponds to TLR7 in the public nomenclature. Applicants argue that the instant specification ascribes several functions to TLRs, and that the oligonucleotide or polynucleotide sequences

derived from TLRs would be useful in the diagnosis of immunological disorders.

Applicants submit a Declaration by Dr. McClanahan asserting that the nucleotide probes from TLR7 DNA sequences may be used to diagnose immunological disorders such as psoriasis and atopic dermatitis. Applicants contend that one of ordinary skill in the art would expect the increase in mRNA levels to correlate with increased TLR7 protein expression, thus the claimed polypeptide would be useful to generate antibodies which could be used in the diagnosis of psoriasis and atopic dermatitis. Applicants also argue that the claimed polypeptide may alternatively be used to generate oligonucleotide probes for use in the diagnosis.

Applicants' arguments have been fully considered, but are not deemed persuasive.

With respect to Applicants' first argument, the amino acid sequence of the claimed polypeptide is set forth in SEQ ID NO:12, which consists of 1045 amino acid residues, however, human TLR7 consists of 1049 amino acid residues, (see attachment sequence comparison "A"). Furthermore, the claimed polypeptide does not seem to be identical to the sequence disclosed for human TLR7, therefore, it appears that the claimed polypeptide and human TLR7 are not one and the same. Even if the claimed polypeptide is human TLR7, Applicants have not established the physiological role of the claimed polypeptide at the time the instant application was filed. With respect to Applicants' argument that the oligonucleotide or polynucleotide sequences derived from TLRs would be useful in the diagnosis of immunological disorders, there is no dispute that members of the TLR family have important physiological significance, however,

however, each member is expressed differentially and appear to respond to different stimuli, therefore, each member has its own physiological role. Furthermore, Applicants have not disclosed a specific disorder that could be diagnosed using the claimed polypeptide or polynucleotide. Instant specification has not expressly or implicitly disclosed that the claimed polypeptide can be used to diagnose psoriasis and atopic dermatitis. Therefore, the post filing data submitted by Dr. McClanahan does not provide a specific and substantial utility for the claimed polypeptide. Although post filing data can be used to substantiate an asserted utility, however, in the instant case there was no assertion that the claimed polypeptide or oligonucleotides derived from it can be used to diagnose psoriasis and atopic dermatitis. Only a general assertion was made that the claimed polypeptide or oligonucleotides derived from it can be used to detect levels of TLRs in a patient having an immunological disorder, (see paragraph 187 of U.S. Publication NO. 2003/0032090), but no specific disorder has been disclosed. Furthermore, even if mRNA levels are increased, it does not always follow that protein levels are also amplified. Thus, the polypeptide of SEQ ID NO:12 lacks a specific or substantial utility, because the specification did not disclose the physiological significance or the biological role of the polypeptide of the instant invention, at the time the instant application was filed.

3b. Claims 1, 23-26 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the action mailed on 29 September 2003, page 6.

Specifically, instant specification has not established a link between the claimed polypeptide or oligonucleotides derived from it and a physiological condition, at the time the instant application was filed.

Therefore, one of ordinary skill in the art would not know how to use the polypeptide of SEQ ID NO:12.

4. ***Declaration under 37 C.F.R §1.132:***

4a. Applicants' declaration under 37 C.F.R §1.132, filed by Dr. McClanahan has been considered, but is insufficient to overcome the rejection of claims 1, 22-26, made under 35 U.S.C. § 101/112.

The declaration submitted by Dr. McClanahan provides data showing that expression levels of TLR7 (which Applicants started referring to the polypeptide of SEQ ID NO:12), is increased in psoriasis skin lesions and atopic dermatitis lesions compared to control normal skin tissue sample. Dr. McClanahan submits that the elevated expression levels of the TLR7 in psoriasis skin lesions and atopic dermatitis lesions, points to the usefulness of the nucleotide sequences derived from the claimed polypeptide in the diagnosis of these diseases.

Firstly, the data submitted by Dr. McClanahan was not disclosed in the instant specification at the time the instant application was filed. Secondly, although post filing data can be used to substantiate an asserted utility, however, in the instant case, no assertion was ever made that the claimed polypeptide or oligonucleotides derived from it can be used to diagnose psoriasis and atopic dermatitis. Therefore, the data submitted by Dr. McClanahan does not provide a specific and substantial utility for the

claimed polypeptide, because there was no explicit or implicit assertion that the claimed polypeptide is useful in diagnosing psoriasis and atopic dermatitis. Thirdly, even if Applicants provide evidence at the time of filing, that shows that TLR7 mRNA levels were elevated in psoriasis and atopic dermatitis, it does not always follow that protein levels are also amplified. Therefore, the fact that mRNA levels might be elevated in psoriasis and atopic dermatitis does not provide a specific and substantial utility for the claimed polypeptide or antibodies that bind to it.

***Conclusion:***

5. No claims is allowed.

***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner

04 April 2004

*Gary L. Kunz*  
**GARY KUNZ**  
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